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PURDY, KYLE A

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/596,159
Filing Date: June 01, 2006
Appellant(s): SMOLA ET AL.

Gary M. Lobel
Reg. No. 51,155
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 05/22/2009 appealing from the Office action mailed 03/04/2009.

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(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

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5,714,472	Gray et al.	02/03/1998
6,194,379	McEwen et al.	02/27/2001

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over McEwen et al. (US 6194379; of record) in view Gray et al. (US 5714472; of record).

Gray is also directed to nutritional compositions for enhancing wound healing. The composition comprises a carbohydrate, a lipid and a protein source (see abstract). The protein source is to comprise about 28% of the caloric content for the composition (see column 3, line 65; see instant claim 4). The composition is also to have an energy density of at least 1.3 kcal/mL (see column 2, lines 15-20; see instant claim 5). It is taught that a high caloric content is useful because it imparts energy to the user. The composition is also taught to contain proline at a caloric percentage of between 4 and 6% (see column 4, lines 63-65; see instant claims 1 and 2). It is taught that proline is useful for accelerating and promoting wound healing and tissue repair/cellular division (see column 4, line 55).

Gray fails to teach the composition as comprising less than 1.8% of the total calories due to arginine.

McEwen is directed to nutritional formulations comprising a protein source, a lipid source and a carbohydrate source (see Example 1). Example 1 teaches a formulation that comprises sucrose, canola oil and arginine. It is taught that arginine is to comprise about 1% of the total caloric content of the composition (see column 9, lines 1-5; see instant claims 1 and 3). It is

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noted that the arginine at such a caloric percentage is capable of accelerating wound healing and nitrogen retention after injury.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Gray and McEwen with a reasonable expectation for success in arriving at a composition comprising a lipid, a protein and a carbohydrate wherein the composition comprises less than 1.8% of the caloric content is attributed to arginine. One would have been motivated to supplement the teaching of Gray with McEwen because the composition would accelerate the healing of wounds and aid in the retention of nitrogen. Therefore, a composition comprising a protein, a carbohydrate and a lipid wherein the composition attributes less than 1.8% of its caloric content to arginine and at least 3% of the total calories of the composition being proline is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in absence of evidence to the contrary.

(10) Response to Argument

In regards to the rejection mailed on 03/04/2009, Appellant contends that the applied rejection is improper and asserts the following:

A) Gray teaches away from McEwen with respect to the amount of arginine required in the composition. Gray explicitly discloses "at least 3% of the total calories" are to be due to arginine. This is in direct contrast to McEwen which discloses composition comprising about 1% arginine with respect to the total calories of the nutritional products. Thus, the skilled artisan would have no reason to combine Gray with McEwen to arrive at the present claims. The

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Examiner has applied hindsight reasoning by attempting to selectively piece together teachings of each reference in an attempt to recreate the instant invention. The skilled artisan would have had no reason to combine the references; and

B) Gray also teaches away from McEwen with respect to the amount of proline used in the composition. Gray teaches using proline in an amount of at least 2.0%, which is in direct contrast to McEwen which fails to disclose the use of proline.

In response to A, the Examiner acknowledges that Gray teaches using arginine in their composition in an amount of at least 3% of the total calories for the composition, which is above that which Appellant is claiming. However, the Examiner respectfully disagrees with Appellants assertion that Gray teaches away from McEwen. Gray is directed to enteral formulations designed for optimized nutrient absorption for accelerating wound healing. It's taught that when arginine is used in an amount of at least 3% of the total caloric content of the composition enhanced wound healing is observed. McEwen is similarly directed to enteral nutritional formulations for improved nutrient absorption. McEwen teaches that their formulation is to comprise arginine in an amount of about 1% of the total caloric content of the composition in order to accelerate wound healing and improve nitrogen retention after injury. Thus, both compositions are quite similar (i.e. enteral formulations for improving nutrient absorption), thereby providing sufficient motivation for one ordinarily skilled in the art to combine them.

With respect to the argument that Gray teaches away from a composition comprising less than 1.8% of the total calories resulting from arginine, the Examiner does not find this argument persuasive. While Gray teaches a value above that instantly claimed, the art as a whole does not

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teach away from using such a value. Lower caloric amounts of arginine have been recognized as useful for improving wound healing. This is exemplified by McEwen which teaches that arginine can accelerate wound healing when present in a composition in an amount of about 1% of the total caloric content. As such, any ordinary person would have had a reasonable expectation for arriving at a composition capable of accelerating wound healing by using an intermediate value between those deemed useful by the prior art, e.g. 1% and 3%. In effect, the combination of references provides a useful working range in which a person could provide arginine to a subject to accelerate wound healing. If such result were the selection of an amount of arginine below 1.8% of the total caloric content, and specific selection of a 1.5% of the calories due to arginine, then such a result would have been a product of ordinary skill and common sense. Moreover, Appellant is directed to MPEP 2144.05 which teaches that a range can be disclosed in multiple prior art references instead of a single prior art reference. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976). "[A] prior art reference that discloses a range encompassing a somewhat narrower claimed range is sufficient to establish a prima facie case of obviousness." *In re Peterson*, 315 F.3d 1325, 1330, 65 USPQ2d 1379, 1382-83 (Fed. Cir. 2003).

It should also be noted that since Gray suggests a mixture of arginine and proline if a final composition implements a mixture of proline and arginine, the relative amounts of each would correspondingly decrease. The teaching of at least 3% arginine refers to the use of arginine alone prior to mixing with proline.

In response to Appellant's argument that the examiner's conclusion of obviousness is

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based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the appellant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). The Examiner has not relied on Appellants disclosure for any part of the instant rejection, rather the Examiner has only relied upon what was known at the time the invention was made. With that said, obviousness can be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion or motivation to do so. In the instant case, there is sufficient motivation to combine the teachings of Gray and McEwen as both prior art references are directed to enteral formulations for improved nutrient absorption. Both references teach using arginine to accelerate wound healing. Thus, based solely on the teachings available in the prior art, all of the elements of Appellants invention were known at the time the invention was made and would have readily been available to one of ordinary skill in the art capable of producing Appellants invention. Appellants arguments are not found persuasive.

In response to B, the Examiner respectfully disagrees. It appears that Appellant is arguing that if two art references do not identically overlap in scope, then they are not combinable. However, this could not be more at odds with the guidance provided by the MPEP. MPEP 2141 states that an 'obviousness rejection is proper if there is some teaching, suggestion or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to

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combine prior art reference teachings to arrive at the claimed invention.’ Further, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). The primary reference to Gray teaches an enteral composition comprising at least 2% of calories due to proline and at least 3% of calories due to arginine. Gray teaches that when arginine and proline are used in these amounts, they accelerate wound healing (see column 4, lines 54-56 and column 6, lines 58-62). Gray fails to teach using arginine in an amount of less than 1.8% of the caloric content for the composition. McEwen cures his deficiency by teaching an enteral composition with lower caloric amounts of arginine, about 1%, which are also taught as useful for accelerating wound healing.

Thus, there is sufficient motivation to combine the two references for producing compositions useful for promoting wound healing. The two teachings at least teach an enteral nutritional composition, both composition exhibit improved nutrient absorption and both employ arginine to accelerate wound healing. And with respect to the argument that Gray teaches away from McEwen, “[t]he prior art’s mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed....” *In re Fulton*, 391 F.3d 1195, 1201, 73 USPQ2d 1141, 1146 (Fed. Cir. 2004). Gray suggests that both proline and arginine enhance wound healing. Gray does not criticize or discredit the use of proline in the composition. Thus, McEwen does not need to teach proline since Gray motivates one to do so. The fact that

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McEwen does not teach proline is not a teaching away from using proline for at least the reasons cited above. Further, it is clear that a proline and arginine combination will be effective and will not have a deleterious effect on wound healing based on Gray's teachings. Appellants arguments are not found persuasive.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

Respectfully Submitted,

/Kyle Purdy/
Examiner, Art Unit 1611
September 2, 2009

Conferees:

/Sharmila Gollamudi Landau/
Supervisory Patent Examiner, Art Unit 1611

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